

**Notice of Allowability**

Application No.

09/245,025

Applicant(s)

GERARD ET AL.

Examiner

Art Unit

Nashaat T. Nashed, Ph. D.

1652

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed May 21, 2004.
2. ☐ The allowed claim(s) is/are 117-120, 123-126, 130-134, 137-140 and 144-147.
3. ☒ The drawings filed on 14 September 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of the:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.  
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  
1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.  
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.  
**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance             |
|   | 9. <input type="checkbox"/> Other _____   |

Nashaat T. Nashed, Ph. D.  
Primary Examiner  
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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 3, 2004 has been entered.

The application has been amended as requested in the communication filed May 21, 2004. Accordingly, claims 122, 127, 136, 141, and 148-213 have been canceled, and claims 119, 120, 123, 125, 126, 128, 133, 134, 137, 139, 140, and 142 have been amended.

Claims 117-121, 123-126, 128-135, 137-140, and 142-147 are pending and under consideration.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Helene C. Carlson on June 10, 2004 and June 24, 2004.

The application has been amended as follows:

In the specification: Replace the paragraph on page 73, starting on line 13 with the following paragraph:

*Mulagenesis of the beta subunit to RNase H<sup>r</sup>.* The RSV RT and AMV RT genes are related [{] [GenBank sequences 102342, J02021 and J02343 (all last revised March 11, 1996) for RSV-C; L10922, L10923, L10924 (all last revised October 4, 1994) for AMV] [}]. These genes code for an identical sequence of amino acids over a short distance of the RNase H region. As described above in Example 1, during the cloning and mutagenesis of the RSV RT genes an RNase H- derivative of the RSV RT  $\beta$  gene was made by site-directed mutagenesis. The oligonucleotide that was used (oligonucleotide #8) changed amino acid Asp450 to an Ala450 and introduced an SsIII site (underlined).

In the claims:

- (i) Delete claims 121, 128, 129, 135, 142, and 143.
- (ii) Rewrite the following claims:

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- Claim 117. A composition for use in reverse transcription of a nucleic acid molecule, said composition comprising two or more viral reverse transcriptases, or mutants or fragments thereof, or combination thereof.
- Claim 120. The composition of claim 117, wherein said reverse transcriptases or mutants or fragments comprise an  $\alpha$  subunit, a  $\beta$  subunit, a  $\beta$ p4 subunit, or a combination thereof.
- Claim 123. The composition of claim 117, wherein at least one of said reverse transcriptases mutants or fragments has substantially reduced RNase H activity compared to the corresponding wild-type reverse transcriptase.
- Claim 124. The composition of claim 117, wherein at least one of said reverse transcriptases mutants or fragments lacks RNase H activity.
- Claim 125. The composition of any of claims 123[[-]] and 124, wherein at least one of said reverse transcriptase mutants or fragments is selected from the group consisting of mutants or fragments of M-MLV ~~MMLV~~, RSV, AMV, RAV, MAV, and HIV reverse transcriptases.
- Claim 126. The composition of any one of claims 123[[-]] and 124, wherein at least one of said reverse transcriptase mutants or fragments comprises an  $\alpha$  subunit, a  $\beta$  subunit, a  $\beta$ p4 subunit, or a combination thereof.
- Claim 130. The composition of claim 117, wherein said reverse transcriptases or mutants or fragments are present in said composition at working concentrations.
- Claim 131. A kit for use in reverse transcription of a nucleic acid molecule, said kit comprising two or more viral reverse transcriptases, or mutants thereof, or fragments thereof, or a combination thereof.
- Claim 133. The kit of claim 131, wherein said reverse transcriptases are selected from the group consisting of ~~MMLV~~ M-MLV, RSV, AMV, RAV, MAV, and HIV reverse transcriptases.
- Claim 134. The kit of claim 131, wherein said reverse transcriptases or mutants or fragments comprise an  $\alpha$  subunit, a  $\beta$  subunit, a  $\beta$ p4 subunit, or a combination thereof.

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- Claim 137. The kit of claim 131, wherein at least one of said ~~reverse transcriptases~~ mutants or fragments has substantially reduced RNase H activity compared to the corresponding wild-type reverse transcriptase.
- Claim 138. The kit of claim 131, wherein at least one of said ~~reverse transcriptases~~ mutants or fragments lacks RNase H activity.
- Claim 139. The kit of any one of claims 137[[-]] and 138, wherein at least one of said ~~reverse transcriptases~~ mutants or fragments is selected from the group consisting of mutants or fragments of M-MLV, MMLV, RSV, AMV, RAV, MAV, and HIV reverse transcriptases.
- Claim 140. The kit of any one of claims 137[[-]] and 138, wherein at least one of said ~~reverse transcriptases~~ mutants or fragments comprises an  $\alpha$  subunit, a  $\beta$  subunit, a  $\beta$ p4 subunit, or a combination thereof.
- Claim 144. The kit of claim 131, wherein said reverse transcriptases or mutants or fragments are present in said kit at working concentrations.

Claims 117-120, 123-126, 130-134, 137-140, and 144-147 are allowed.


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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